S2000 Ultrasound System 510(k) Submission

KO87142

NOV 1 3 2008

510(k) Summary Prepared October 27, 2008

Sponsor:

Siemens Medical Solutions, Inc.,

Ultrasound Division 1230 Shorebird Way

Mountain View, California 94043

Contact Person:

Shelly Pearce

Telephone:

(650) 694-5988

Fax:

(650) 694-5580

Submission Date:

October 13, 2008

Device Name:

Acuson S2000™Ultrasound System

Common Name:

Diagnostic Ultrasound System

Classification:

Regulatory Class: Ш Review Category: Tier II Classification Panel: Radiology

Ultrasonic Pulsed Doppler Imaging System FR # 892.1550 Ultrasonic Pulsed Echo Imaging System

Diagnostic Ultrasound Transducer

FR # 892.1560 FR # 892.1570 Product Code 90-IYN Product Code 90-IYO Product Code 90-ITX

A. Legally Marketed Predicate Devices

The Acuson S2000™Ultrasound System is substantially equivalent to the Acuson Antares Ultrasound System.

B. Device Description:

The Acuson S2000™ has been designed to meet the following product safety standards:

- UL 60601-1, Safety Requirements for Medical Equipment
- IEC 60601-2-37 Diagnostic Ultrasound Safety Standards
- CSA C22.2 No. 601-1, Safety Requirements for Medical Equipment
- AIUM/NEMA UD-3, Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment
- AIUM/NEMA UD-2, Acoustic Output Measurement Standard for Diagnostic Ultrasound
- 93/42/EEC Medical Devices Directive
- Safety and EMC Requirements for Medical Equipment
 - EN/IEC 60601-1
 - EN/IEC 60601-1-1
 - EN/IEC 60601-1-2
- IEC 1157 Declaration of Acoustic Power
- ISO 10993-1 Biocompatibility

S2000 510(k) Submission

Page 7 of 43

C. Intended Use

The S2000™ ultrasound imaging systems are intended for the following applications: Fetal, Abdominal, Intraoperative, Pediatric, Small Parts, Transcranial, OB/GYN, Cardiac, Pelvic, Neonatal/Adult Cephalic, Vascular, Musculoskeletal, Superficial Musculoskeletal, and Peripheral Vascular applications.

The system also provides the ability to measure anatomical structures {fetal, abdominal, intraoperative, intraoperative neurological, pediatric, small organ, neonatal cephalic, adult cephalic, cardiac, trans-esophageal, transrectal, transvaginal, peripheral vessel, musculo-skeletal (conventional), musculo-skeletal (superficial) and neonatal cardiac} and calculation packages that provide information that provide information to the clinician that may be used adjunctively with other medical data obtained by a physician for clinical diagnosis purposes.



Food and Drug Administration 9200 Corporate Boulevard Rockville MD 20850

NOV 1 3 2008

Ms. Shelly Pearce Regulatory Affairs Siemens Medical Solutions USA, Inc. P.O. Box 7393, 1230 Shorebird Way MOUNTAIN VIEW CA 94039

Re: K082142

Trade/Device Name: Acuson S2000™ Diagnostic Ultrasound System

Regulation Number: 21 CFR 892.1550

Regulation Name: Ultrasonic pulsed doppler imaging system

Regulatory Class: II

Product Code: IYN, IYO, and ITX

Dated: September 17, 2008 Received: September 22, 2008

Dear Ms. Pearce:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the Acuson S2000™ Diagnostic Ultrasound System, as described in your premarket notification:

Transducer Model Number

CW2 Probe
CW5 Probe
EC9-4 Curved Array
9L4 Linear Array
14L5 Multi-D Array
4P1 Phased Array
6C2 Curved Array
4C1 Curved Array
4V1 Phased Array

10V4 Phased Array
14L5 SP Linear Array
7CF2 Curved Array
9EVF4 Curved Array
V5Ms Multiplane TEE
17L5HDS Linear Array
18L6 HD Linear Array
8V3 Phased Array

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the <u>Federal Register</u>.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

If you have any questions regarding the content of this letter, please contact Lauren Hefner at (240) 276-3666.

Joyce M. Whang, Ph.D.

Sincerely yours

Acting Director, Division of Reproductive,

Abdominal, and Radiological Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure(s)

1.3 Indications for Use

510(k) Number (if known):

√ 052142

Device Name: S2000™Diagnostic Ultrasound System

Indications for Use:

The S2000™ ultrasound imaging systems are intended for the following applications: Fetal, Abdominal, Intraoperative, Pediatric, Small Parts, Transcranial, OB/GYN, Cardiac, Pelvic, Neonatal/Adult Cephalic, Vascular, Musculoskeletal, Superficial Musculoskeletal, and Peripheral Vascular applications.

The system also provides the ability to measure anatomical structures (fetal, abdominal, intraoperative, intraoperative neurological, pediatric, small organ, neonatal cephalic, adult cephalic, cardiac, trans-esophageal, transrectal, transvaginal, peripheral vessel, musculo-skeletal (conventional), musculo-skeletal (superficial) and neonatal cardiac) and calculation packages that provide information that provide information to the clinician that may be used adjunctively with other medical data obtained by a physician for clinical diagnosis purposes.

Prescription UseX_ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use (21 CFR 801 Subpart C)
(PLEASE DO NOT WRITE BELO	W THIS LINE-COI	NTINUE ON ANOTHER PAGE IF NEEDED;
Concurrence of	f CDRH, Office of	Device Evaluation (ODE)

S2000 510(k) Submission

Page 12 of 43

(Division Sign-Off)

Division of Reproductive, Abdominal and

Radiological Devices

510(k) Number

K082142

1.3 Indications for Use Forms

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name:

ACUSON \$2000 Ultrasound System

Intended Use:

Ultrasound imaging or fluid flow analysis of the human body as follows:

				,		N	lode of Oper	ation		
Clinical Application	Α	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic		L.,	L							
Fetal		Р	Р	Р	Р	Р	Р		BMDC	Note 2,3,4,5,7,8,10,
Abdominal		P	Р	Р	Р	ρ	Р		BMDC	Note 2,3,4,5,7,8,10,
Intraoperative (Note 9)		Р	P	þ	Ρ	Р	Р		BMDC	Note 2,3,4,5,7,8,10,
Intraoperative Neurological		Р	Р	P		Р	Р	,	BMDC	Note 2,3,4,5,7,8,10,
Pediatric		P	Р	Р	Р	P	P		BMDC	Note 2,3,4,5,7,8,10,
Small Organ (Note 1)		Р	Р	Р	Р	Р	Р		BMDC	Note 2,3,4,5,7,8,10,
Neonatal Cephalic		Р	ρ¯	Р	Р	Р	Р		BMDC	Note 2,3,4,5,7,8,10
Adult Cephalic		Ρ	Р	P	Р	Р	Р		BMDC	Note 2,3,4,5,7,8,10
Cardiac		<u>.</u> P	Р	Р	Р	P	P		BMDC	Note 2,3,4,5,6,7,8,1
Trans-esophagea!		P	P	Ъ	Р	Р	Р		BMDC	= 10, . 10 (0 (7)= 1
Transrectal		Р	P	Р		Р	Р		BMDC	Note 2,3,4,5,7,8,10, 11,14
Transvaginal		Р	₽	P.		Р	Р		вмос	Note 2,3,4,5,7,8,10,
Transurethral										
Intravascular										
Peripheral vessel		6	Ρ	Ρ	P	Р	Р		ВМДС	Note2,3,4,5,6,7,8,10
Laparoscopic										17,17
Musculo-skeletal Conventional		Р	Р	Р	Р	Р	Р		BMDC	Note 2,3,4,5,7,8,10,
Musculo-skeletal Superficial		Р	P	Р	Ρ	Р	Р		BMDC	Note 2,3,4,5,7,8,10,
Other (specify) Neonatal Cardiac	[P	Р	Р	Р	Р	Р		BMDC	Note 3,4,6

N = new indication; P = previously cleared by FDA, K072786; E = added under Appendix E

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.

Note 2 Note 3

Ensemble itssue harmonic imaging SieClear multi-view spatial compounding Tissue Equalization Technology Note 4

Note 5 3-Scape real-time 3D imaging

Note 6

Note 7

Cadence contrast agent imaging 8&W SieScape panoramic Imaging Power SieScape panoramic imaging For example: vascular, abdominal Note 8

Note 10 Clarify VE vascular enhancement technology
Note 11 Advanced Sieclear multi-view spatial compounding
Note 13 STIC

Note 13 STIC

Note 14 eSie™ Touch elasticity Imaging

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.10

S2000 510(k) Submission

Page 13 of 43

(Division Sign Off)

Division of Reproductive, Abdominal and

Radiological Devices

510 (k) Number (if known):

Device Name: Intended Use:

CW2 Probe for use with ACUSON \$2000

Ultrasound imaging or fluid flow analysis of the human body as follows:

	<u> </u>					M	ode of Opera	noite		
Clinical Application	Α	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal					Р			-		
Abdominal					P					
Intraoperative (Note 9)					Р		·			
Intraoperative Neurological										· · · · · · · · · · · · · · · · · · ·
Pediatric		<u> </u>			Р				1	
Small Organ (Note 1)					Р	res				
Neonatal Cophalic					Р		i	·	1.**	
Adult Cephalic					Р	•			1	
Cardiac					Р					
Trans-esophageal										
Transrectal										-
Transvaginal										
Transurethral								···	1	
Intravascular									 	
Peripheral vessel					Р				i	
Laparoscopic										· · · · · · · · · · · · · · · · · · ·
Musculo-skeletal Conventional					Р					* *
Musculo-skeletal Superficial					Р					
Other (specify)										• • • • • • • • • • • • • • • • • • • •

N = new indication; P = previously cleared by FDA K# 063803, K072786; E = added under Appendix E

Additional Comments:

Note 1 For example: breast, testes, thyroid, penis, prostate, etc. Note 9 For example: vascular, abdominal

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED) Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

S2000 510(k) Submission

Page 14 of 43

(Division Sign-Off)

Division of Reproductive, Abdominal and

Radiological Devices

510 (k) Number (if known);

Device Name:

CW5 Probe for use with ACUSON \$2000

Intended Use:

Ultrasound imaging or fluid flow analysis of the human body as follows:

						М	ode of Open	alion		
Clinical Application	A	В	м	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal					P		<u> </u>	-	 	
Abdominal	Ι''''	T			Р		†		·	
Intraoperative (Note 9)					Р					
Intraoperative Neurological										
Pediatric					P					
Small Organ (Note 1)					P					
Neonatal Cephalic					P				····	
Adult Cephalic					P		t			
Cardiac					Р		† 			
Trans-esophageal										
Transrectal										
Transveginal										·······
Transurethral										
Intravascular										
Peripheral vessel					P					
Laparoscopic						·				
Musculo-skeletal Conventional					Р					
Musculo-skeletal Superficial					Р					
Other (specify)										

N = new Indication; P = previously cleared by FDA K# 063803, K072786; E = added under Appendix E

Note 1 For example; breast, testes, thyroid, penis, prostate, etc.

Note 9 For example; vascular, abdominal

> (PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED) Concurrence of CDRH, Office of Device Evaluation (ODE)

> > Prescription Use (Per 21 CFR 801.109)

\$2000 510(k) Submission

Page 15 of 43

(Division Sign-Off)

Division of Reproductive, Abdominal and

Radiological Devices

510 (k) Number (if known):

Device Name:

EC9-4 Curved Array Transducer for use with ACUSON S2000

Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

							Mode of Op	eration		
Clinical Application	А	8	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		P	Р	Р		Р	Р	-	BMDC	Note 2,3,4,5,7,8,10, 11
Abdominal		Р	Р	Р		P	Р		BMDC	Note 2,3,4,5,6,.7,8,10, 11
intraoperative Abdominal										110.0 2,0,7,0,0,7,0,10, 11
Intraoperative Neurological										
Pediatric										
Small Organ (Note 1)		Þ	Р	Р		Р	Р		вмос	Note 2,3,4,5,7,8,10, 11,14
Neonatal Cephalic		Р	Р	Р		Р	P		BMDC	Note 2,3,4,5,7,8,10
Adult Cephalic										11010 2,0,7,0,10
Cardiac										
Trans-esophageal										
Transrectal		Р	Ρ	Р		Р	P		ВМДС	Note 2,3,4,5, 6, 7,8,10, 11,14
Transvaginal		Р	P	P		Р	Р		вмас	Note 2,3,4,5,7,8,10, 11
Transurethral										Total deligition of th
Intravascular										
Peripheral vessel			\neg						-	
Laparoscopic						-				
Musculo-skeletal Conventional										
Musculo-skeletai Superficial										
Other (specify)							·			

N = new indication; P = previously cleared by FDA K# 063803, K072786; E = added under Appendix E

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.

Note 2

Ensemble tissue harmonic imaging SieClear multi-view spatial compounding Tissue Equalization Technology Note 3 Note 4

Note 5 Note 6 3-Scape real-time 3D imaging

Cadence contrast agent imaging

Note 7 B&W SieScape panoramic imaging
Note 8 Power SieScape panoramic imaging
Note 10 Clarify VE vascular enhancement technology

Note 11 Advanced Sieclear multi-view spatial compounding

Note 12

Note 14 eSie™ Touch elasticity imaging

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED) Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

S2000 510(k) Submission

Page 16 of 43

(Division Sign-Off)

Division of Reproductive, Abdominal and

Radiological Devices

510 (k) Number (if known):

Device Name: Intended Use: 9L4 Linear Array Transducer for use with ACUSON \$2000

Ultrasound imaging or fluid flow analysis of the human body as follows:

	L						Mode of C	peration		
Clinical Application	Α	В	М	PWO	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										<u> </u>
Felal		ρ	P	P		Р	Р		BMDC	Note 2,3,4,5,7,8,10, 11
Abdominal										
Intraoperative Abdominal										
intraoperative Neurological										
Pediatric		P	Р	Р		Р	P		BMDC	Note 2,3,4,5,7,8,10, 11
Small Organ (Note 1)		Р	Р	Р		P	P	***************************************	ВМДС	Note 2,3,4,5,6,7,8,10, 11,14
Neonatal Cephalic		Р	Р	Р		P	P		вирс	Note 2,3,4,5,7,8,10, 11
Adult Cephalic		_								
Cardiac								·		· · · · · · · · · · · · · · · · · · ·
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral			****							
Intravascular								-		
Peripheral vessel		Р	Р	Р		Þ	Р		вмос	Note 2,3,4,5,6, 7,8,10, 11, 14
Laparoscopic			-							
Musculo-skeletal Conventional		Р	Р	Р		Р	Р		вмрс	Note 2,3,4,5,6,7,8,10, 11, 14
Musculo-skeletal Superficial		Р	P	ρ		Р	Р		вмос	Note 2,3,4,5,6,7,8,10, 11, 14
Other (specify)										

N = new indication; P = previously cleared by FDA K# 063085, K072786; E = added under Appendix E

Additional Comments:

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.

Note 2

Ensemble tissue harmonic imaging SieClear multi-view spatial compounding Tissue Equalization Technology Note 3

Note 4 Note 5 3-Scape real-time 3D imaging

Note 5
Cadence contrast agent imaging
Note 7
B&W SieScape panoramic imaging
Note 8
Power SieScape panoramic imaging
Note 10
Clarify VE vascular enhancement technology

Note 11 Advanced Slectear multi-view spatial compounding

Note 12

Note 14 eSie™ Touch elasticity imaging

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED) Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

S2000 510(k) Submission

Page 17 of 43

(Division Sign-Off)

Division of Reproductive, Abdominal and

Radiological Devices

510 (k) Number (if knowп):

Device Name:

4P1 Phased Array Transducer for use with ACUSON \$2000

Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

		,				N	lode of Oper	ration		The state of the s
Clinical Application	A	В	м	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		P	Р	P	P	. Б	Р		BMDC	Note 2,3,4,5,7,8,10
Abdominal		Р	P	Р	P	P	P		BMDC	Note 2,3,4,5,7,8,10
Intraoperative Abdominal				The state of the s			<u> </u>		000	Note 2,5,4,5,7,6,10
Intraoperative Neurological										-
Pediatric			<u> </u>				——————————————————————————————————————			·
Small Organ						·· · · · · · · · · · · · · · · · · · ·	<u>-</u>			
Neonatal Cephalic										
Adult Cephalic		Р	P	Р	P		Р		BMDC	Note 2 2 4 5 7 8 40
Cardiac		Р	Р	P	Р	P	P		BMDC	Note 2,3,4,5,7,8,10
Trans-esophageal							<u> </u>		UMDO	Note 2,3,4,5,6,7,8,10
Transrectal										
Transvaginal							1			
Transurethral										
Intravascular										
Peripheral vessel										· · · · · · · · · · · · · · · · · · ·
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)			$\neg \neg$							

N = new indication; P = previously cleared by FDA K# 063803, K072786; E = added under Appendix E

Additional Comments:

Ensemble tissue harmonic imaging Note 2

Note 3 Note 4 SieClear multi-view spatial compounding

Note 5 Note 6

Tissue Equalization Technology
3-Scape real-time 3D imaging
Cadence contrast agent imaging
B&W SiaScape panoramic imaging Note 7

Note 8 Power SieScape panoramic imaging
Note 10 Clarify VE vascular enhancement technology

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED) Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

S2000 510(k) Submission

Page 19 of 43

(Division Sign-Off)

Division of Reproductive, Abdominal and

Radiological Devices

510 (k) Number (if known):

Device Name: Intended Use:

6C2 Curved Array Transducer for use with ACUSON \$2000

Ultrasound imaging or fluid flow analysis of the human body as follows:

						М	ode of Opera	ation		
Clinical Application	A	В.	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic				L						
Fetal		Р	Р	Р		Þ	Ρ		BMDC	Note 2,3,4,5,7,8,10,
Abdominal		þ	Р	Р		P	Р	•••••	BMDC	Note 2,3,4,5,7,8,10,
Intraoperative Abdominal						-				11,114
Intraoperative Neurological								· · · · · · · · · · · · · · · · · · ·		······································
Pediatric		P	ъ	Р		Р	Р		вмос	Note 2,3,4,5,7,8,10,
Small Organ		mi								
Neonatal Cephalic		i''							<u> </u>	
Adult Cephalic					-					
Cardiac										
Trans-esophageal										·····
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		Р	Р	Р		P	Р		BMDC	Note 2,3,4,5,7,8,10,
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; P = previously cleared by FDA K# 063085, K072786; E = added under Appendix E

Additional Comments:

Note 2 Ensemble tissue harmonic imaging
Note 3 SieClear multi-view spatial compounding
Note 4 Tissue Equalization Technology

Note 4 Note 5

Note 5

Scape real-time 3D imaging
Note 7

B&W SieScape panoramic imaging
Note 8

Power SieScape panoramic imaging
Note 10

Clarify VE vascular enhancement technology

Note 11 Advanced Sieclear multi-view spatial compounding Note 14 eSle™ Touch elasticity imaging

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED) Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

S2000 510(k) Submission

Page 20 of 43

(Division Sign-Off)

Division of Reproductive, Abdominal and

Radiological Devices

510 (k) Number (if known):

Device Name: Intended Use: 4C1 Curved Array Transducer for use with ACUSON \$2000

Ultrasound imaging or fluid flow analysis of the human body as follows:

						М	ode of Open	ation		
Clinical Application	А	В	М	PWD	CWD.	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specity)	Other (Specify)
Ophthalmic										
Fetal		P	Р	P	Р	Р	Р		ВМОС	Note 2,3,4,5,7,8,10,
Abdominal		Р	Р	Р	Ρ	P	Р		BMDC	Note2,3,4,5,6,7,8, 10, 11, 14
Intraoperative Abdominal										10, 11, 14
Intraoperative Neurological										
Pediatric							 			
Small Organ		Р	P	Ρ	Р	P	P	····	BMOC	· · · · · · · · · · · · · · · · · · ·
Neonatal Cephalic		-							DW:00	
Adult Cephalic										
Cardiac		P	P	P	P	P	P		BMDC	
Trans-esophageal					Ť		1		550	
Transrectal								· · · ·		
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		Р	P	Р	P	₽	Р		BMDC	
Laparoscopic				\neg						
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)				1	···					

N = new indication; P = previously cleared by FDA K# 063085, K072786, K032114; E ≈ added under Appendix E

Additional Comments:

Note 2 Ensemble tissue harmonic imaging Note 3

SieClear multi-view spatial compounding
Tissue Equalization Technology
3-Scape real-time 3D imaging
Cadence contrast agent imaging Note 4

Note 5

Note 6

Note 7

B&W SieScape panoramic imaging

Note 8

Power SieScape panoramic imaging

Note 10

Clarity VE vascular enhancement technology Note 11 Advanced Sieclear multi-view spatial compounding

Note 12

Note 14 eSie™ Touch elasticity imaging

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED) Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

S2000 510(k) Submission

Page 21 of 43

(Division Sign-Off)

Division of Reproductive, Abdominal and Radiological Devices 510(k) Number 510(k)

510 (k) Number (if known):

Device Name: Intended Use: 4V1 Phased Array Transducer for use with ACUSON \$2000

Ultrasound imaging or fluid flow analysis of the human body as follows:

						M	ode of Oper	ation		
Clinical Application	A	В	М	PWD	CWD	Color Dappler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic				Ĭ		-				
Felai		Р	Р	P		P	P		BMDC	Note 2,3,4,5,7,8,10
Abdominal		Р	Р	Р		P	Р		BMDC	Note 2,3,4,5,7,8,10,
Intraoperative Abdominal										17
Intraoperative Neurological										
Pediatric										
Small Organ	-								 	
Neonatal Cephalic							-			
Adult Cephalic										
Cardiac									 	
Trans-esophageal										
Transrectal									· · · · · · · · · · · · · · · · · · ·	
Transvaginal										
Transurethral									-	
Intravascular										
Peripheral vessel										
Laparoscopic										
Musculo-skeletal Conventional				_						
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; P = previously cleared by FDA K# 063085, K072788; E = added under Appendix E

Additional Comments:

Note 2 Ensemble tissue harmonic imaging

SieClear multi view spatial compounding
Tissue Equalization Technology
3-Scape real-time 3D imaging
B&W SieScape panoramic imaging Note 3 Note 4

Note 5

Note 7

Note 8

Power SieScape panoramic imaging

Note 10

Clarity VE vascular enhancoment technology

Note 11

Advanced Sieclear multi-view spatial compounding

eSie™ Touch elasticity imaging

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED) Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

S2000 510(k) Submission

Page 22 of 43

(Division Sign-Off)

Division of Reproductive, Abdominal and

Radiological Devices

510 (k) Number (if known):

Device Name: Intended Use:

10V4 Phased Array Transducer for use with ACUSON \$2000 Ultrasound imaging or fluid flow analysis of the human body as follows:

						M	lode of Oper	ration		
Clinical Application	А	В	м	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic	[1 rise (1 in lane - 0,000)		
Fetal		P	Р	Р	Р	Р	Р		BMDC	Note 2,3,4,5,7,8,10
Abdominal		Ρ	P	ρ	P	P	P		BMDC	Note 2,3,4,5,7,8,10
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric		Р	Ρ	ь	P	ρ	Р		BMDC	Note 2,3,4,5,7,8,10
Small Organ										
Neonatal Cephalic		Ρ	P	P	P	Р	Р		ВМОС	Note 2,3,4,5,7,8,10
Adult Cephalic										
Cardiac		Р	Р	Р	Р	P	Р		BMDC	Note 3,4
Trans-esophageal									-	
Transrectal										
Transvaginal										······································
Transurethral										
Intravascular							7			
Peripheral vessel		Ρ,	Ρ	P	Р	P	Р		BMDC	Note 2,3,4,5,7,8,10
Laparoscopic						***************************************				
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)					1					

N ≈ new indication; P = previously cleared by FDA K# 063085, K072786; E = added under Appendix E

Additional Comments:

Note 2 Ensemble tissue harmonic imaging

Note 3 SieClear multi view spatial compounding

Note 4 Tissue Equalization Technology

Note 5
Scape real-time 3D imaging
Note 7
B&W SieScape panoramic imaging
Note 8
Power SieScape panoramic Imaging
Note 10
Clarify VE vascular enhancement technology

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED) Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

\$2000 510(k) Submission

Page 23 of 43

(Division Sign-Off)

Division of Reproductive, Abdominal and Radiological Devices X82142

510 (k) Number (if known):

Device Name: Indications For Use:

14L5 SP Linear Array Transducer for use with ACUSON S2000 Diagnostic imaging or fluid flow analysis of the human body as follows:

	F7 Sector					М	ode of Opera	ation		
Clinical Application	Α	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Olher (Specify)
Ophthalmic		1.								
Fetal									1 -	
Abdominal							T			
Intraoperative (Note 9)		Р	P	Р		₽	Р	***************************************	BMDC	Note 2,3,4,5,7,8,10
Intraoperative Neurological		Ρ	Р	Р		Р	Р		вмос	Note 2,3,4,5,7,8,10,
Pediatric							1			
Small Organ (Note 1)		Р	Р	Р		Р	Р		BMDC	Note 2,3,4,5,7,8,10,
Neonatal Cephalic										(1,77
Adult Cephalic						****				
Cardiac										
Transesophageal										·
Transrectal										
Transvaginal						·				
Transurethral								······································		
Intravascular										
Peripheral vessel		P	₽	Р		Р	Р		BMDC	Note2,3,4,5,6 ,7,8,10, 11,14
Laparoscopic										14,0,10,11,14
Musculo-skeletal Conventional		Р	Р	Р		₽	Р		BMDC	Note 2,3,4,5,7,8,10,
Musculo-skeletat Superficial										11,14
Other (specify)										

N = new indication; P = previously cleared by FDA K# 063085, K072786; E = added under Appendix E

Additional Comments:

Note 1	For example: breast, testes	, thyroid,	penis,	prostate, e	etc.
--------	-----------------------------	------------	--------	-------------	------

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

S2000 510(k) Submission

Page 24 of 43

(Division Sigh-Off)

Division of Reproductive, Abdominal and

Radiological Devices 1

Note 2 Ensemble lissue harmonic imaging

Note 3 SieClear multi-view spatial compounding Tissue Equalization Technology 3-Scape real-time 3D imaging

Note 4

Note 5

Note 6 Note 7

Cadence contrast agent imaging B&W SieScape panoramic imaging Power SieScape panoramic imaging For example: vascular, abdominal Note 8

Note 9

Note 10 Clarify VE vascular enhancement technology

Note 11 Advanced Sieclear multi-view spatial compounding Note 14 eSie™ Touch elasticity imaging

510 (k) Number (if known):

Device Name: Intended Use:

7CF2 Curved array mechanical 3D transducer for use with ACUSON \$2000

Ultrasound imaging or fluid flow analysis of the human body as follows:

		Mode of Operation								
Clinical Application	A	В	м	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		Р	Р	Р		Р	Р		BMDC	Note 2,3,4,5,7,8,10, 11,13
Abdominal		Р	Р	Р		P	Р		BMDC	Note 2,3,4,5,7,8,10,
Intraoperative Abdominal										11, 13
Intraoperative Nourological	1									
Pediatric										
Small Organ										
Neonatal Cephalic							-			
Adult Cephalic										
Cardiac										
Trans-esophageal										
Transrectal						·	*******			
Transvaginal						-				
Transurethrai						~				
Intravascular		一					 i			·
Peripheral vessel										· · · · · · · · · · · · · · · · · · ·
Laparoscopic						·				
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)	T	[I							

N = new indication; P = previously cleared by FDA K# 063803, K072786; E = added under Appendix E

Additional Comments:

Note 2 Ensemble tissue harmonic imaging

SieClear multi-view spatial compounding Tissue Equalization Technology

Note 4 Note 5 3-Scape real-time 3D imaging

Note 7 B&W SieScape panoramic imaging
Note 8 Power SieScape panoramic imaging
Note 10 Clarity VE vascular enhancement technology

Note 11 Advanced Sieclear multi-view spatial compounding Note 13 STIC

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED) Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

S2000 510(k) Submission

Page 25 of 43

(Division Sign-Off)

510 (k) Number (if known):

Device Name: Intended Use:

9EVF4 Curved Array Transducer for use with ACUSON S2000 Ultrasound imaging or fluid flow analysis of the human body as follows:

							-		,	
 						М	ode of Oper	ation	7 (
Clinical Application	A	В	м	PWD	CWD	Calar Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		P	P	Ρ		þ	Р		BMDC	Note 2,3,4,5,7,8, 10,11
Abdominal		1								10,11
Intraoperative Abdominal				· · · · · ·		***		u-t		
Intraoperative Neurological										
Pediatric										
Small Organ	I									
Neonatal Cephalic		Ρ	Р	Р		Р	Р		BMDC	Note 2,3,4,5,7,8,
Adult Cephalic										10,11
Cardiac										
Trans-esophageal										
Transrectal										·
Transvagina!		Þ	P	P		Þ	P		BMDC	Note 2,3,4,5,7,8,
Transurethra!						· · · · · · · · · · · · · · · · · · ·				10,77
Intravascular										
Peripherał vessel										
Laparoscopic										
Musculo-skeletal Conventional									*	
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; P = previously cleared by FDA K# 063803, K072786; E = added under Appendix E

Additional Comments:

Ensemble tissue harmonic imaging

Note 2 Note 3 Note 4 SieClear multi-view spatial compounding
Tissue Equalization Technology
3-Scape real-time 3D imaging
B&W SieScape paparamic imaging

Note 5

Note 8 Power SieScape panoramic imaging
Note 10 Clarify VE vascular enhancement technology

Note 11 Advanced Sieclear multi-view spatial compounding

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED) Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

S2000 510(k) Submission

Page 26 of 43

(Division Sign-Off)

Division of Reproductive, Abdominal and

Radiological Devices

510 (k) Number (if known);

Device Name: intended Use:

V5Ms Multiplane TEE Transducer for use with ACUSON \$2000 Ultrasound imaging or fluid flow analysis of the human body as follows:

		Mode of Operation										
Clinical Application	A	В	м	PWD	CWD	Color Dopp ie r	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)		
Ophthalmic												
Felal									 			
Abdominal								·····	 	<u>-</u>		
Intraoperative Abdominal						*						
Intraoperative Neurological												
Pediatric												
Small Organ						~ · · · · · · · · · · · · · · · · · · ·	 					
Neonatal Cephalic							†					
Adult Cephalic							<u> </u>					
Cardiac	1						f					
Trans-esophageal		P	Р	Р	Р	P	P		вмос			
Transrectal						<u> </u>	· · · · · · · · · · · · · · · · · · ·		DIVIDO	**		
Transvaginal												
Transurethral							 					
Intravascular							 					
Peripheral vessel												
Laparoscopic												
Musculo-skeletal Conventional						•••						
Musculo-skeletal Superficial												
Other (specify)						W1						

N = new indication; P = previously cleared by FDA K# 063803, K072786; E = added under Appendix E

Additional Comments: r/a

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED) Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

S2000 510(k) Submission

Page 27 of 43

(Division Sigh-Off)

Division of Reproductive, Abdominal and

Radiological Devices

510 (k) Number (if known):

Device Name: Intended Use:

17L5HDS Linear Array Transducer for use with ACUSON \$2000 Ultrasound imaging or fluid flow analysis of the human body as follows:

						M	ode of Oper	ation		
Clinical Application	Α	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal									1	
Abdominal	 									
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric			İ							
Small Organ (Note 1)		Р	Р	Р		P	Р		вмос	Note 2,3,4,5,7,8,10, 11,14
Neonatal Cephalic		•								
Adult Cephalic	1									
Cardiac				İ						
Trans-esophageal	L									
Transrectal		<u> </u>			<u> </u>					
Transvaginal			ŀ	ľ						
Transurethral										
Intravascular										
Peripheral vessel		Р	Р	Р		P	Р		BMDC	Note 2,3,4,5,7,8,10, 11,14
Laparoscopic										
Musculo-skeletat Conventional		Р	Р	Р		Р	Р		BMDC	Note 2,3,4,5,7,8,10, 11,14
Musculo-skeletal Superficial		Р	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10, 11,14
Other (specify)	1									

N = new indication; P = previously cleared by FDA K# 063085, K072786; E = added under Appendix E

Additional Comments:

- For example: breast, testes, thyroid, penis, prostate, etc. Ensemble tissue harmonic imaging SieClear multi-view spatial compounding Note 1 Note 2
- Note 3 Tissue Equalization Technology
- Note 4
- Note 5 Note 7
- 3-Scape real-time 3D imaging 8&W SieScape panoramic imaging Power SieScape panoramic imaging Note 8
- Note 10 Clarify VE vascular enhancement technology
- Note 11 Advanced Sieclear multi-view spatial compounding Note 14 eSie™ Touch elasticity imaging

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED) Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

S2000 510(k) Submission

Page 28 of 43

(Division Sign-Off)

Division of Reproductive, Abdominal and

Radiological Devices +

510 (k) Number (if known):

Device Name: Intended Use:

18L6 HD Linear Array Transducer for use with ACUSON S2000 Ultrasound imaging or fluid flow analysis of the human body as follows:

		Mode of Operation									
Clinical Application	A	В	М	PWD	cwo	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)	
Ophthalmic											
Fetal							ľ				
Abdominal	\vdash										
Intraoperative Abdominal											
Intraoperative Neurological											
Pediatric							<u> </u>				
Small Organ (Note 1)		N	N	Z		N	N		BMDC	Note 2,3,4,5,7,8,10 11,14	
Neonatal Cephalic					}		Ì				
Adult Cephalic	Ì										
Cardiac											
Trans-esophageal											
Transrectal]	<u></u>					
Transvaginal	ĺ					•	1				
Transurethral				I	L						
Intravascular	<u> </u>					<u> </u>					
Peripheral vessel		N	Z	N		N	N		BMDC	Note 2,3,4,5,7,8,10 11,14	
Laparoscopic											
Musculo-skeletal Conventional		N	N	N		N	N		BMDC	Note 2,3,4,5,7,8,10 11,14	
Musculo-skeletat Superficial		N	N	N		N	N		BMDC	Note 2,3,4,5,7,8,10 11,14	
Other (specify)	1			ī —	[Ĭ				

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Additional Comments:

For example: breast, testes, thyroid, penis, prostate, etc. Note 1

Note 2 Ensemble tissue harmonic imaging

SieClear multi-view spatial compounding
Tissue Equalization Technology
3-Scape real-time 3D imaging
B&W SieScape panoramic imaging Note 3

Note 4

Note 5

Note 7 Power SieScape panoramic imaging

Note 10 Clarify VE vascular enhancement technology

Note 11 Advanced Sleclear multi-view spatial compounding Note 14 eSie™ Touch elasticity imaging

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED) Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

S2000 510(k) Submission

Page 29 of 43

(Division Sign-Off)

Division of Reproductive, Abdominal and

Radiological Devices

510 (k) Number (if known):

Device Name: Intended Use: 8V3 Phased Array Transducer for use with ACUSON \$2000

Ultrasound imaging or fluid flow analysis of the human body as follows:

	L	Mode of Operation									
Clinical Application	A	В	м	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)	
Ophthalmic								İ			
Fetal		٩	Р	P	Р	Р	P		BMDC	Note 2,3,4,5,7,8,10	
Abdominal											
Intraoperative Abdominal											
Intraoperative Neurological											
Pediatric]	P	Р	Р	Р	Р	Р		BMDC	Note 2,3,4,5,7,8,10	
Small Organ	1										
Neonatal Cephalic		Р	Р	P	Р	Р	P		BMDC	Note 2,3,4,5,7,8,10	
Adult Cephalic								-		1-	
Cardiac		P	Ρ	P	Р	Р	Р		8MDC	Note 3,4,6	
Trans-esophageal											
Transrectal								1			
Transvaginal						10.700.00					
Transurethral											
Intravascular											
Peripheral vessel						<u></u>				7**	
Laparoscopic											
Musculo-skeletal Conventional											
Musculo-skeletal Superlicial						-					
Other (specify) Neonatal Cardiac		Ρ	Р	Р	Р	P	Р		BMDC	Note 3,4,6	

N = new indication; P = previously cleared by FDA K# 063095, K072786; E = added under Appendix E

Additional Comments:

Note 2	Ensemble tissue harmonic imaging
Mate 0	ClaClass and the class and the

SieClear mutti-view spatial compounding
Tissue Equalization Technology
3-Scape real-time 3D imaging
Cadence contrast agent imaging Note 3 Note 4

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

S2000 510(k) Submission

Page 30 of 43

(Division Sign-Off)

Division of Reproductive, Abdominal and

Radiological Devices

510(k) Number __

Note 5

Note 7 B&W SieScape panoramic Imaging
Note 8 Power SieScape panoramic Imaging
Note 10 Clarity VE vascular enhancement technology